

(d) identifying as a hER β -interactive compound any compound that reduces the binding of said labelled ligand to hER β .

25. A method as defined in claim 24, wherein said ligand is 17- β estradiol.

26. A method as defined in claim 24, wherein said hER β -interactive compound is an agonist.

27. A method as defined in claim 24, wherein said hER β -interactive compound is an antagonist.

REMARKS

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. §121:

- I. Claims 17 to 18 drawn to isolated polypeptide comprising SEQ ID No:2 or fragments thereof, defining class 530, subclass 350.
- II. Claims 1-16, drawn to isolating nucleic acid of SEQ ID NO:2 encoding the polypeptide of SEQ ID NO:1 and the vectors encoding, cells containing the afore-mentioned expression vectors and a method of production and recovery of said protein from said cells, classifying class 536, subclass 23.1, for example.
- III. Claim 23, drawn to antibody that binds to hER β , classified in class 530, subclass 387.9, for example.

IV. Claims 19-22, drawn to a method for identifying hER β -interactive compounds, classified in class 435, subclass 7.1 for example.

In response, solely to be responsive to the requirement for restriction, applicants hereby elect the claims of Group I, claims 17-18, with traverse.

At the outset, applicants note that the claims of Group II, 1-16, were cancelled when the application was filed. Accordingly, a restriction should be between Groups I, III, and IV.

Applicants further submit that the claims of Group IV, 19-22, should be considered together with the claims of Group I, 17-18. This is because the claims of Group IV relate to methods of identifying compounds that interact with the unique polypeptide claimed in Group I. These groups of claims are related, as the Examiner noted, as product and process of use. The Examiner contends that the proteins may be used for the production of antibodies of Group III, thus substantiating a basis for requiring restriction between these two sets of claims.

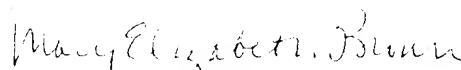
Applicants respectfully transverse this ground for rejection.

Using the novel products of Group I in any process requires determining the novelty of the products of Group I. Once the novelty of these products is established, methods of using these products are patentable. *In re Ochiai*, 37 USPQ 2d. 1127 (Fed. Cir.1995). In addition, 35 U.S.C. §103(b) mandates that "a biotechnological process (in the present case, identifying hER β -interactive compounds) using or resulting in a composition of matter that is novel under Section 102 and

nonobvious under Section 103(a) shall be considered non-obvious if claims to the process and the composition of matter are contained in the same application for patent ..." 35 U.S.C. §103(b)(1)(A). Thus even if the process of using the proteins represents patentably distinct subject matter, this subject matter should nevertheless be considered with the product claims.

Accordingly, applicant submit that the Examiner should modify the requirement for restriction and consider claims 17-22 and new claims 24-27 in the same application.

Respectfully submitted,



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Docket No: 0646/1D205 US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ramesh A. BHAT; Ruth HENDERSON; Chulai HSIAO;
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For: NOVEL HUMAN ESTROGEN RECEPTOR-BETA

**MARK-UP FOR RESPONSE TO RESTRICTION REQUIREMENT
PURSUANT TO 37 C.F.R. § 1.121**

17. A purified polypeptide comprising a sequence selected from the group consisting of the sequence depicted in Figure [1] 4 SEQ ID NO:2 and function-conservative variants thereof.

18. A purified polypeptide comprising amino acids 1-45 of the sequence depicted in Figure [1] 4 SEQ ID NO:2.

19. A method for identifying hER β -interactive compounds, said method comprising:

(a) contacting[purified hER β] the polypeptide of claim 17 with a labelled ligand in the presence of test compounds, to form test reactions, and in the absence of test compounds, to form control reactions;

(b) incubating said test and control reactions under appropriate conditions to achieve equilibrium binding of said labelled ligand to hER β ;

(c) determining the level of binding of said labelled ligand to hER β in said test and control cultures; and

(d) identifying as a hER β -interactive compound any compound that reduces the binding of said labelled ligand to hER β .

20. A method as defined in claim 19, wherein said ligand is 17- β estradiol.

21. A method as defined in claim 19, wherein said hER β -interactive compound is an agonist.

22. A method as defined in claim 19, wherein said hER β -interactive compound is an antagonist.